REMARKS

Claims 1-44 are pending in this application. Claims 10-15, 21-30, and 34-44 are withdrawn from consideration as drawn to non-elected invention. New claims 45-49 have been added. Thus, claims 11-9, 16-20, 31-33, and 45-49 are under consideration. Support for new claims 45-49 can be found at least in original claim 1 and on page 20, lines 8-15 where relative homology is discussed.

35 U.S.C. § 112, first paragraph

Claims 1, 4-9, 16, 18-20, 31 and 33 are rejected under 35 U.S.C. § 112, ¶ 1, for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the are that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the Examiner has rejected claims 1, 4-9, 16, 18-20, 31 and 33 for the recitation of "substantially the same as SEQ ID NO: 1" or "fragments of SEQ ID NO: 1." The Examiner contends that the disclosure "fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 1 alone is insufficient to describe the genus." The Examiner also asserts that the recitation of "fragments of SEQ ID NO: 1" includes fragments "as small as a single nucleotide," and that combining this phrase with the term "having" must therefore encompass "every single DNA molecule isolated since the beginning of time." Applicants respectfully traverse the rejection.

The Examiner is attempting to interpret the meaning of words in the claims the have been ascribed specific meaning in the specification, without the use of said specification. The specification can be used in interpreting claim language when the specification provides definitions for terms appearing in the claims. *In re Vogel*, 422 F.2d 438, 441 164 USPQ 619, 612 (CCPA 1970). Specifically, the term "fragment" is defined on page 16, lines 13-23. Using this definition, the Examiner cannot properly construe the claims to "include fragments as small as a single nucleotide," as such an interpretation would not be possible in light of the definition

of "fragment" which clearly stipulates that a nucleic acid "fragment" means a "subsequence of the nucleic acid which is of a sufficient size and confirmation to properly function as a hybridization probe, as a primer in a polymerase chain reaction [(PCR)], to code for a polypeptide or polypeptide fragment, or in another manner characteristic of nucleic acids (page 16, lines 18-23)." Thus, a single nucleic acid cannot be a "fragment" as it cannot be a hybridization probe, a primer for PCR, or code for a polypeptide. Furthermore, as a "fragment" of claim 1 must be a subsequence of claim 1 as defined by the specification, this cannot include, as the Examiner suggests, "every single DNA molecule isolated since the beginning of time," even in light of the Examiner's interpretation of "having" as being open and equivalent to "comprising."

Furthermore, the phrase "substantially the same as" is also given meaning in the specification. The specification on page 19, line 24 through page 20, line 15 clearly states what the applicants intend by the phrase "substantially the same as." Specifically, the specification shows that for sequence A to be substantially the same as sequence B, sequence A must "retain the functions" of B, but differs from B by the "substitution, deletion, and or addition of one or more nucleotides, and/or by the incorporation of some other advantageous feature into the nucleic acid..."

Moreover, the preamble of the claim sets forth a limitation to the claim, which the Examiner has failed to apply. In particular, the claims recite that the nucleic acid must be "specific to *Histoplasma capsulatum*." It is a well established feature of patent law that "if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim (MPEP 2111.02; *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999))." Moreover, "[a]ny terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation." *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.* 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989). Clearly, the phrase "specific to *Histoplasma capsulatum*" limits the claim to those sequences that are "specific to *Histoplasma*

capsulatum." As defined on page 15, lines 7-23, "specific to *H. capsulatum*" limits the claim to antigens that "contain at least one epitope which is not common to other related fungi or other microorgansisms." Thus, the claims must be read with the limitation of "contain[ing] at least one epitope not common to other related fungi or other microorgansisms" in mind, and cannot include every "DNA molecule isolated since the beginning of time," as few if any of those isolated would meet the limitation of being "specific to *Histoplasma capsulatum*." Thus, the claims define the distinguishing, common attributes of this genus through, at least, the requirement that the nucleic acid be specific to *H. capsulatum*.

Moreover, applicants have amended claim 1 to recite "specific to *H. capsulatum* M antigen." Thus amendment clearly defines in the preamble exactly to what portion of *H. capsulatum* the claimed genus must be specific. Support for this added language can be found throughout the specification. Applicants note that as this added recitation is merely providing the name for SEQ ID NO. 1 and therefore this amendment in know way limits the scope of the claims as it merely states what is obvious to one of skill in the art and was clear as previously written.

Therefore, the claims do not as the Examiner suggests, encompass every "DNA molecule isolated since the beginning of time," or single nucleic acids. Neither do the claims read on a genus that is highly variant. In fact, the claims encompass a very specific genus relating to the structure (ie. the sequence) and the function of SEQ ID NO: 1, its complementary sequence, and fragments thereof. Applicants believe this rejection to be overcome and respectfully request it be withdrawn.

35 U.S.C. § 112, second paragraph

Claims 1, 4-5, 8-9, 16, 18, 20, 31 and 33 are rejected under 35 U.S.C. § 112, ¶ 2, for allegedly containing subject matter which is indefinite. In particular, the Examiner alleges that the phrase "substantially the same as" is vague and indefinite. The Examiner states that it is unclear what constitutes the metes and bounds of the invention in light of this phrase and

proposes that it is unclear when a DNA molecule is considered "substantially the same (e.g., 99%, 90%, 70%, 40%, etc.)." Applicants respectfully traverse this rejection.

As noted above, the phrase "substantially the same" has a very specific meaning given in the specification. The specification on page 19, line 24 through page 20, line 15 clearly states what the applicants intend by the phrase "substantially the same as." Specifically, the specification shows that for sequence A to be substantially the same as sequence B, sequence A must "retain the functions" of B, but differs from B by the "substitution, deletion, and or addition of one or more nucleotides, and/or by the incorporation of some other advantageous feature into the nucleic acid..." Furthermore, the definition in the specification states that sequences that are substantially the same as a given sequence will have less than about 10% divergence from the sequence or its complement (page 20, lines 8-11). Given this definition, the Examiner is incorrect in asserting that the claims are indefinite for the recitation "substantially the same as," as this phrase has a very specific meaning and creates a very discernable range for which a sequence can be considered substantially the same. Applicants note that new claims 45-49 do not recite the phrase "substantially the same as" and as such, cannot be held indefinite for the recitation of the phrase "substantially the same as." Applicants believe this rejection is overcome, and respectfully request its withdrawal.

35 U.S.C. § 102

Claims 1-9, 16- 20, and 31-33 are rejected under 35 U.S.C. § 102(a), for allegedly being anticipated by Zancope-Oliveira et al. (1994) *Clin. and Diag. Lab. Immunol.* 1(5):563-8. Applicants respectfully traverse this rejection. Applicants respectfully point out that the cited publication represents the applicants' own work as every author listed is also an inventor. The finding in Applied Materials, Inc. v. Gemini Research Corp., stands for the proposition that a disclosure (in that case a patent application) which discloses a later claimed invention, shows that the invention was invented before the disclosure date. In that case, because the disclosure was by the inventors only, it was evidence of the invention thereof by the applicants of the later-filed

application. Applied Materials, Inc. v. Gemini Research Corp., 835 F.2d 279, 5, USPQ2d 1127 (Fed. Cir, 1987) reh'g granted, opinion modified, 15 USPQ2d 1816 (Fed. Cir. 1988). Similarly in the event that the cited reference fully discloses the invention claimed in the present application, the cited art could not be 102(a) prior art as the invention had to be invented before the publication date of the citation. Additionally, as the Examiner is no doubt aware, the requirements for inclusion as an inventor are different from those of authorship. Furthermore, it is not necessary nor required for applicants to explain why an inventor was excluded from authorship for a publication. Such decisions are outside the providence of the U.S. PTO. Applicants believe this rejection to be overcome and respectfully request its withdrawal.

Claims 1and 4-9 are rejected under 35 U.S.C. § 102(b), for allegedly being anticipated by Stryer (BIOCHEMISTRY 3rd edition, New York, 1988, page 72). The Examiner's rejection is based on the term "fragment" being interpreted to include single nucleic acid fragments and thus is anticipated by Stryer for the disclosure of Adenine, Guanine, Thymine, and Cytosine. Applicants respectfully point out that, as noted above, the term "fragment" read in light of the definition in the specification can not be interpreted as a single nucleotide. Furthermore, as amended the preamble states that the nucleic acid of the claim must be "specific to *H. capsulatum* M antigen," any anticipatory sequence must also be specific to the M antigen of *H. capsulatum*. Stryer does not disclose any such sequence. Nor does Stryer disclose SEQ ID NO: 1. Thus, no reading of Stryer can create a situation in which Stryer anticipates the claim. Applicants believe this rejection to be overcome and respectfully request its withdrawal.

Claims 1, 4-9, 16, 18- 20, 31 and 33 are rejected under 35 U.S.C. § 102(e), for allegedly being anticipated by Lee et al., U.S. Patent No. 5,693,501 (the '501 patent). The Examiner contends that the claims of the present application comprise a nucleic acid comprising SEQ ID NO:1, substantially the same as SEQ ID NO: 1, and fragments of SEQ ID NO:1. The Examiner then contends that the sequences disclosed in the '501 patent are substantially the same as SEQ ID NO:1. Applicants respectfully point out that the Examiner is incorrect. The '501 patent does not disclose any sequence of the M antigen of *H. capsulatum* or its complement or any fragment

thereof. Rather, it discloses sequences of the *H. capsulatum* rRNA gene internal transcribed spacer region I (ITSI). Furthermore, the '501 patent does not disclose a sequence substantially the same as SEQ ID NO: 1. The Examiner's basis for this rejection revolves around the incorrect interpretation of the phrase "substantially the same as." As previously discussed, the phrase "substantially the same as" has specific meaning given to it by the specification. This meaning creates limitations as to the degree of divergence from SEQ ID NO: 1 that is permitted. Anyone of skill in the art would understand that rRNA-encoding DNA is not substantially similar to M antigen-encoding DNA. The '501 patent does not meet this requirement. Thus, the '501 patent cannot anticipate any of the claim of the present application. Applicants believe this rejection to be overcome and respectfully request it be withdrawn.

Pursuant to the above amendments and remarks, reconsideration and allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

Enclosed is Credit Card Payment Form PTO-2038 authorizing payment in the amount of $420.00 (two-month extension of time fee). No additional fee is believed due; however, the Commissioner is hereby authorized to charge any additional fees which may be required or to credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence and any items indicated as attached or included are being transmitted via facsimile transmission to: Examiner Albert Mark Navarro, Art Unit 1645 at (703) 308-4242 on the date indicated below.

Gwendolyn D. Spratt — 11-19-03

Gwendolyn D. Spratt — Date